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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
| 09/282,879 | 03/31/1999 | SUBROTO CHATTERJEE | 46906-2-DIV | · 9227 | |
| 21874 | 7590 06/23/2003 | • | | | |
| EDWARDS & ANGELL, LLP | | | EXAM | EXAMINER | |
| P.O. BOX 9 BOSTON, M | | | RAO, MANJUNATH N | | |
| | | | ART UNIT | PAPER NUMBER | |
| | | | 1652 | | |
| | | | DATE MAILED: 06/23/2003 | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application N . | Applicant(s) | | | | | |
|--|-----------------------------------|---------------------|---------------|--|--|--|--|
| Advisory Action | 09/282,879 | CHATTERJEE, SUE | BROTO | | | | |
| navioury notion | Examiner | Art Unit | | | | | |
| | Manjunath N. Rao, Ph.D. | 1652 | | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address | | | | | | | |
| THE REPLY FILED 29 May 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. | | | | | | | |
| PERIOD FOR REPLY [check either a) or b)] | | | | | | | |
| a) The period for reply expiresmonths from the mailing date of the final rejection. b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | | |
| 1. A Notice of Appeal was filed on 29 May 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal. | | | | | | | |
| 2. The proposed amendment(s) will not be entered because: | | | | | | | |
| (a) they raise new issues that would require further consideration and/or search (see NOTE below); | | | | | | | |
| (b) they raise the issue of new matter (see Note b | | | malifying the | | | | |
| (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or | | | | | | | |
| (d) they present additional claims without canceling a corresponding number of finally rejected claims. | | | | | | | |
| NOTE: | | | | | | | |
| 3. Applicant's reply has overcome the following rejecti | on(s): | | | | | | |
| 4. Newly proposed or amended claim(s) would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s). | | | | | | | |
| 5. ☑ The a) ☐ affidavit, b) ☐ exhibit, or c) ☑ request for reconsideration has been considered but does NOT place the application in condition for allowance because: <u>See attached</u> . | | | | | | | |
| 6. The affidavit or exhibit will NOT be considered becaraised by the Examiner in the final rejection. | ause it is not directed SOLELY to | o issues which were | e newly | | | | |
| 7. ☑ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☑ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended. | | | | | | | |
| The status of the claim(s) is (or will be) as follows: | | | | | | | |
| Claim(s) allowed: | | | | | | | |
| Claim(s) objected to: | | | | | | | |
| Claim(s) rejected: <u>13-17, 31</u> . | | | | | | | |
| Claim(s) withdrawn from consideration: | | | | | | | |
| 8. $\hfill \square$ The proposed drawing correction filed on is | a)☐ approved or b)☐ disapp | roved by the Exami | ner. | | | | |
| 9. Note the attached Information Disclosure Statemer | nt(s)(PTO-1449) Paper No(s) | · | • | | | | |
| 10. Other: | | | | | | | |
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Advisory Action

Claims 1-22 are still at issue and are present for examination.

Applicants' amendments and arguments filed on 5-29-03, paper No.24, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. While amendments to claim 13 overcome the rejections under 35 U.S.C. § 112, Ist and 2nd paragraphs, such amendments and arguments do not overcome the rejection of claims 13-17, 31 under 35 U.S.C. 103(a). In response to the previous Office action, applicants have traversed the above rejection basing some of their arguments as in their previous response, i.e., none of the references provide prior protein or nucleic acid sequence etc. and submit a Declaration by the inventor, arguing that it would not have been obvious to those skilled in the art to obtain the amino acid sequence of the purified enzyme found in the prior art and arrive at the recombinant enzyme. Examiner respectfully disagrees with such an argument. Applicant argues that the purified protein was difficult to sequence and that an alternate method had to be adopted in order to obtain the cDNA clone, wherein the alternate method comprised raising antibodies to purified enzyme and using the expression cloning technique. While this may have been the case, Examiner takes the position, that such techniques would have been obvious to those skilled in the art and is also the route taken to clone proteins with a blocked N-terminal. In response to Examiner's argument that applicants have not shown any specific difference between the recombinant and the natural, purified enzyme found in the prior art, applicants have argued that natural enzyme had tightly associated proteases and phosphatases and the recombinant N-Smase enzyme was more stable than the natural enzyme. However, such arguments are also not persuasive to overcome the above rejection. The contamination of other enzymes depends on

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the source from which the natural enzyme was isolated and would be well within the knowledge of those skilled in the art to improve on purification method. Applicants have also not shown that the stability of the recombinant enzyme is a character that was imparted just because of rendering the enzyme recombinant and furthermore, the stability is not a claim limitation. Therefore, even if the recombinant enzyme had the same level or a higher level of stability as the natural enzyme, the claims would continue to be obvious. Examiner applies the same argument for the unwanted proteolytically digested products during storage of natural enzyme.

Therefore, while the request to reconsider has been considered and entered, none of the claims are in condition for allowance. For reasons of record, the rejection of claims under 35 U.S.C. 103(a) is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.

Manjunath N. Rao June 19, 2003